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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/289,290	08/11/1994	RALPH H. WEICHSELBAUM	ARCD:086/SER	1375

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EXAMINER

LI, QIAN J

ART UNIT PAPER NUMBER

1632

DATE MAILED: 05/08/2002

[Handwritten signature]

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/289,290

Applicant(s)

WEICHELBAUM ET AL.

Examiner

Janice Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6, 8-14, 17-21 and 26-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 8-14, 17-21 and 26-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *detailed action*.

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DETAILED ACTION

The Group and Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to examiner Q. Janice Li, at Group Art Unit 1632.

Claims 22-25 have been canceled in BRIEF ON APPEAL, claims 4, 5, 7, 15, and 16 have been canceled in Amendment filed concurrently with Appellents' Brief. Currently, claims 1-3, 6, 8-14, 17-21, and 26-36 are pending in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The previous rejection of 1, 3, 6, 8-14, 17-21, 26-30, and 35 under 35 U.S.C. 112, first paragraph, has been reversed by the Board of Patent Appeals and Interferences.

The pending claims are drawn to a process of treating a human cancer patient comprising providing to a cancer cell in said patient a DNA sequence encoding a radiosensitizing polypeptide operatively linked to a constitutive promoter and contacting said cell with ionizing radiation whereby the gene is expressed and the cancer is treated.

In the specification, a large number of molecules are contemplated for use as "radiosensitizing polypeptide", ranging from cytokines (IL-1, IL-6, or TNF-alpha), to growth factors (bFGF) and receptors, to free radical scavenger (MnSOD), to tumor suppressor genes (p53, Rb gene), and to cytotoxic genes (HSVtk and cytosine deaminase). The examiner notes that these molecules do not share a substantial structural feature essential to a common utility, they possess diverse physiological functions, operate in different manners *in vivo*, and via different biological pathways. In addition, a person of ordinary skill in that art would not envision one in view of the other. However, in view of the decision of the Board, the previous rejection is withdrawn.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 6, 8-14, 17-21, and 26-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are vague and indefinite because of the term "gene". The term "gene" refers not only to a coding sequence but also to an entire genomic structure, including introns and all regulatory regions upstream and downstream of coding sequences, it is unclear whether these extra sequences would interfere with the constitutive promoters, and whether the applicants intend to claim so. The metes and bounds of the claims are unclear.

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These claims are vague and indefinite because the recited term "increasing" is a relative term, it is unclear what would be the baseline level for increased transcription, for example, and thus, the metes and bounds of the claims are unclear.

Claim 8 recites the limitation "the transfection". There is insufficient antecedent basis for this limitation in the claim.

Claim 36 recites the limitation "said polypeptide" in step (b). There is insufficient antecedent basis for this limitation in the claim.

Claim 36 is vague and indefinite because it is incomplete. The claim calls for assessing the response of a cell in the preamble and in step (d), however, there is no active step or criteria set forth in the claim. It is unclear what criteria the method is assessing to determine the cell response, thus, the metes and bounds of the claim are unclear. Method claims need not recite all operating details but should at least recite positive, active steps so that the claims will set out and circumscribe a particular area with a reasonable degree of precision and particularity and make clear what subject matter that claims encompass as well as make clear the subject matter from which others would be precluded, *Ex parte Erlich*, 3 USPQ2d 1011 at 6.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The prior rejections of claims 1-3, 6, 8-14, 17-21, 26-28, and 31-36 under 35 U.S.C. 103(a) as being unpatentable over Hallahan et al in view of Teng et al, Neta et al are reversed by the Board of Patent Appeals and Interferences, and are thereby withdrawn.

The prior rejections of claims 29 and 30 under 35 U.S.C. 103(a) as being unpatentable over Hallahan et al in view of Teng et al, Neta et al are vacated and requested for remand by the Board of Patent Appeals and Interferences.

A new ground of rejection necessitated by the Board decision appears below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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Claims 29 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by *Zhang et al* (US6,143,290).

Claims are drawn to a pharmaceutical composition comprising a genetic construct comprising a gene that encodes a cell radiosensitizing or radioprotecting factor operatively linked to a constitutive promoter dispersed in a pharmacologically acceptable carrier, wherein the genetic construct is packaged with a virion or virus particle.

Zhang et al teach an adenovirus construct comprising a p53 coding sequence and optionally packaged in virions (abstract and the last paragraph in column 2), which p53 is taught by the specification as one of the radiosensitizing agents (page 7, line 4) of instant specification). *Zhang et al* go on to teach that the p53 expression region is under the control of a strong constitutive promoter such as a CMV promoter or SV40 (column 3, lines 64-66), and is dispersed in a pharmaceutically acceptable solution or buffer (column 5, lines 1-5). Thus, *Zhang et al* anticipate the instant claims.

Claims 29 and 30 are rejected under 35 U.S.C. 102(a) as being anticipated by *Walther et al* (Anticancer Res 1993 Sept;13:1565-74).

Walther et al teach a vector construct encoding TNF-alpha packaged in a retrovirus particle (paragraph bridging page 1565-66, and 2nd paragraph in left column of 1566). They introduce the recombinant retrovirus into tumor cells causing constitutive expression of TNF-alpha and reduction of tumor growth (abstract). They further introduce the recombinant virus subcutaneously into nude mice. Apparently their in vivo

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and in vitro use of the recombinant virus indicates that the recombinant virus is dispersed in a pharmacologically acceptable carrier. Thus, *Walther et al* anticipate instant claims.

Claims 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by *Uzvolgyi et al* (Cell Growth Differ 1991 Jun;2:297-303).

Uzvolgyi et al teach a vector construct encoding human Rb cDNA packaged in a retrovirus particle (1st paragraph under Materials and Methods, page 301), which Rb is taught by the specification as one of the radiosensitizing agents (page 7, line 5 of instant specification). *Uzvolgyi et al* introduce the recombinant retrovirus into tumor cells causing constitutive overexpression of Rb protein in these cells (abstract). Apparently the use of the recombinant virus in cells indicates that the recombinant virus is dispersed in a pharmacologically acceptable carrier. Thus, *Uzvolgyi et al* anticipate instant claims.

Conclusion

Claims 29 and 30 are rejected.

Claims 1-3, 6, 8-14, 17-21, 26-28, and 31-36 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

QJL
May 2, 2002

~~JAMES KETTER~~
PRIMARY EXAMINER


JAMES KETTER
PRIMARY EXAMINER

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